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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,926	04/02/2004	Chien-Hsuan Han	21077-8	9426

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,926	HAN ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13 - 17, 20, 21, 23, 24, 58, 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 - 17, 20, 21, 23, 24, 58, 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed February 3, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – 1st Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 13 – 17, 20, 21, 23, 24, 58 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed November 3, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that when the application is viewed in its entirety, the invention is described in sufficient detail in order meet the written description provision. In vitro dissolution profiles are given and examples of materials which can be used and nine examples are given which exemplify the types of formulation contemplated by the present invention.

These arguments are not found to be persuasive. A number of the examples prepared appear not to fall within the scope of the invention. For example, the seeds

prepared in examples 1 and 2 (p 32 of the specification) appear to only contain immediate release baclofen and the baclofen tablets prepared in examples 8 and 9 (p 36 and 37) do not appear to contain both an immediate and controlled release component. Only example 6 appears to be within the scope of the invention as it contains both immediate and controlled release baclofen. The instant application provides no link between the dissolution profiles in the figures and the examples prepared in the specification. Thus, one of ordinary skill reading the instant application does not know what formulation(s) result in the claimed release profile and whether the variations in the release profiles shown are the results in changing the relative proportion of various ingredients in the dosage form or from the use of different controlled release materials. Therefore, a representative number of formulations which provide the claimed release profile have not been described in sufficient detail to support the full genus of dosage forms which provide the claimed baclofen release profile.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 13 – 16, 20, 21, 23, 24, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (US 4,780,463) in view of Vishwanathan et al. (US 2002/0119192). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed November 3, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that the amended claims exclude the polymers taught by Vishwanathan et al., namely carboxyvinyl polymers. Sunshine et al. fails to appreciate the unique absorption profile of baclofen and fails to

provide any guidance to a skilled artisan on how to formulate a sustained release baclofen formulation. The skeletal muscle relaxants contemplated by Sunshine in a sustained release form list in Table IV does not include baclofen.

These arguments are not found to be persuasive. The claims of the instant application have not been amended in such a way as to exclude the ingredients that Applicant argue are now excluded from the claims. While in claim 13, the dosage form consists essentially of an immediate and a controlled release component, the immediate release component comprises a $GABA_B$ agonist and at least one pharmaceutically acceptable excipient so the ingredients in this component are completely open. Thus, the presence of immediate release analgesic as taught by Sunshine et al. is not excluded. The controlled release component consists essentially of a $GABA_B$ agonist, at least one pharmaceutically acceptable excipient and a controlled release material selected from a Markush group which does not contain carboxyvinyl polymers. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 (**MPEP 2111.03**; emphasis added). Thus, the presence of other controlled release polymers is not excluded because of the absence of a clear definition of "consisting essentially of" in the claims or specification and because the claims are also not closed as the controlled release polymer can be "a pharmaceutically acceptable excipient".

New claim 57 recites a dosage form that consists of an immediate and a controlled release component, but the immediate release component comprises a $GABA_B$ agonist and at least one pharmaceutically acceptable excipient so the ingredients in this component are completely open. Thus, the presence of immediate release analgesic is not excluded. The controlled release component consists of a $GABA_B$ agonist, at least one pharmaceutically acceptable excipient and a controlled release material selected from a Markush group which does not contain carboxyvinyl polymers. The presence of other controlled release polymers is not excluded as more than one pharmaceutically acceptable excipient can be present in the formulation.

The teachings of a prior art reference are not limited to the examples but is prior art for all that it discloses. While baclofen is not explicitly identified or prepared in a dosage form with both an immediate and sustained release component, five other components listed in the table of centrally-acting skeletal muscle relaxants in table III are prepared in such a dosage form and shown in table IV. Thus, Sunshine et al. discloses that a number of centrally-acting skeletal muscle relaxants can be delivered in a dosage form with both an immediate and sustained release component.

While Sunshine et al. does not identify the location of optimal baclofen absorption, Vishwanathan et al. discloses that baclofen is one drug that is absorbed predominantly in the upper parts of the gastrointestinal tract (¶ [0032]). "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). **MPEP 2144.05**. The exact release profile

claimed would be the result of routine experimentation by one of ordinary skill in the art given the teaching of Vishwanathan et al. would prepare dosage form in which the baclofen was released in the upper parts of the gastrointestinal tract for optimal absorption of the active ingredient.

7. Claims 13 – 17, 20, 21, 23, 24, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. and Vishwanathan et al. further in view of Fara (US 2003/0031711). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed November 3, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Fara is relied solely upon for the teaching of racemic baclofen and does not cure the deficiencies of Sunshine et al. and Vishwanathan et al.

These arguments are not found to be persuasive. As discussed above, Sunshine et al. and Vishwanathan et al. are not deficient and therefore Fara is not required to cure those deficiencies. Therefore this rejection is maintained.

8. Claims 13 – 16, 20, 21, 23, 24, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al and Vishwanathan et al. further in view of Patel et al. (US 6,248,363). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed November 3, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Patel et al. is relied solely upon for teaching capsules comprising discrete units and does not cure the deficiencies of Sunshine et al. and Vishwanathan et al.

These arguments are not found to be persuasive. As discussed above, Sunshine et al. and Vishwanathan et al. are not deficient and therefore Patel et al. is not required to cure those deficiencies. Therefore this rejection is maintained.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW